## REMARKS

Claims 1-19 and 21-50 are now pending in this application. Claims 1-37 are rejected. Claims 2 and 5-15 are objected to. Claim 20 is cancelled herein. New claims 38-50 are added. Claims 1-19 and 21-37 are amended herein to place them in better form and/or to clarify the invention. The specification has been amended to place it in better form.

Claims 2 and 5-15 and various portions of the specification have been objected to as having misspelled words. The term "characterised" has been changed in the claims and specification. The term "homogenisation" has been changed in the claims but not in the specification since the term "homogenisation" is the same as "homogenization" and both are accepted spellings of the term at issue since "homogenisation" is merely the British spelling of the term.

Claims 9, 10, 13, and 37 have been rejected under 35 U.S.C. § 112, second paragraph, as indefinite. The Office Action states that claims 9, 10, and 37 are narrative. Claims 9, 10, 13, and 37 have been amended to be in better form. Applicants respectfully request that the indefiniteness rejection be withdrawn.

Claims 16-37 have been rejected under 35 U.S.C. § 101 as reciting a use with no method steps. Claims 16-37 have been amended to include active process steps. Applicants respectfully request that the rejection under 35 U.S.C. § 101 be withdrawn.

Claims 1-37 have been rejected under 35 U.S.C. § 103(a) as obvious over Müller et al. (European Journal of Pharmaceutics and Biopharmaceutics, 2000, Vol. 50, pp. 161-177) in view of Kreitlow et al. (Journal of Biotechnology, 1999, Vol. 70, pp. 61-63), and in view of Caudales et al. (International Journal of Systematic and Evolutionary Microbiology, 200, 50, pp. 1029-1034), and further in view of Viseras et al. (International Journal of Pharmaceutics, 1999, Vol. 182, pp. 7-20), and further in view of Jacob et al. (Life Sciences, Vol. 66, No. 25, pp. 2433-2439), and further in view of Walker et al. (New Zealand Journal of Botany, 1997, Vol. 35, pp. 396-384), and further in view of Chairungsrilerd et al. (European Journal of Pharmacology, 1996, Vol. 314, pp. 351-356).

To establish a *prima facie* case of obviousness, it is necessary to show that all the claim limitations are taught or suggested by the prior art. *See In re Royka and Martin*, 180 USPQ 580, 583, 490 F.2d 981 (CCPA 1974).

Claim 1 recites microparticles and/or nanoparticles produced from biomasses of lipid-containing microalgae, macroalgae, marine fungi, cyanobacteria, or marine bacteria. Müller et al. fails to disclose or suggest this limitation. Müller et al. does not describe lipid-nanoparticles from marine organisms. The Solid Lipid Nanoparticles ("SLNs") disclosed in Müller et al. are a synthetic product. There is no disclosure in Müller et al. that the SLNs are obtained from marine biomasses or that the SLNs can be obtained from marine biomasses. Also, the Office Action fails to provide any reason for one of ordinary skill in the art to go through the

expense of fabricating SLNs from naturally present fatty acids from marine biomasses. Moreover, the cited art fails to disclose or suggest how to fabricate SLNs from the naturally present fatty acids from marine biomasses, especially in light of the low melting point of the naturally present fatty acids. Additionally, the Office Action has not addressed what one of ordinary skill in the art would do in the event that a physicochemically unstable system (phase separation) were to occur in the preparation of these SLNs from marine organisms. Additionally, microparticles and nanoparticles from marine organisms may contain pigments, vitamins, flavionites, saponites, proteins, and minerals, which the SLNs of Müller et al. do not contain. Such concerns have not been addressed in Müller et al. or in the Office Action. Additionally, there is no indication in Müller et al. that a prediction could have been made that the ingredients of biomasses through the conversion into microparticles and nanoparticles would be better available and would provide surprising characteristics, such as to prevent nosocomial infections, and to provide immune-stimulating characteristics and scavenger characteristics. Thus, the combination of Müller et al. with any document disclosing the use of marine organism lipids is not appropriate. Additionally, as explained above, Müller et al. is directed to synthetic lipids and one of ordinary skill in the art would not replace them with marine organism lipids at least because of all of the unresolved issues disclosed above. The Supreme Court has made clear that a claim composed of several elements "is not proved obvious merely by demonstrating that

each of its elements was, independently, known in the prior art" and stated the importance of identifying "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *See KSR International Co. v. Teleflex Inc. et al.* 82 USPQ2d 1385, 1396 (2007). In light of the above, one of ordinary skill in the art would not be prompted to combine a reference which discloses the use of marine organism lipids with Müller et al. so as to replace the synthetic lipid particles disclosed in Müller et al. with particles from marine organisms. Additionally, none of the cited art discloses or suggests the production of SLNs from marine organisms.

Also, an advantage of the present invention is that through the conversion of marine biomasses into microparticles and nanoparticles, the advantageous characteristics of the marine biomasses are better available. Even if one skilled in the art knows that marine biomasses contain specific ingredients and is familiar with the technology of Müller et al., no knowledge would be present that the combination of marine biomasses and their conversion into microparticles and nanoparticles results in a synergistic effect.

Kreitlow et al. fails to disclose or suggest any microparticles or nanoparticles of lipids from marine organisms. Additionally, Kreitlow et al. includes no disclosure to predict or otherwise make obvious that the ingredients of marine biomasses through conversion into microparticles and nanoparticles would

be better available and would exhibit surprising characteristics, such as the prevention of nosocomial infections. Additionally, as explained above, Müller et al. is directed to synthetic lipids and the disclosure of Kreitlow et al. is therefore not combinable with Müller et al. Thus, the attempt to combine Müller et al. and Kreitlow et al. as described in the Office Action is based on inappropriate hindsight interpretation and one of ordinary skill in the art would have no reason to combine those two references.

Similarly, Caudales et al. also fails to disclose or suggest any microparticles or nanoparticles of lipids from marine organisms and does not provide any reason for one of ordinary skill in the art to replace the synthetic SLNs of Müller et al. with marine biomasses. Accordingly, the combination of Müller et al. and Caudales et al. is also inappropriate.

Additionally, Caudales et al. fails to disclose that the cyanobacteria have substantially complex mixtures of mono-, di-, and triglycerides and also fails to disclose the cyanobacteria having substantial fatty acids with chain lengths of noticeably different sizes. Consequently, since these are important characteristics for Müller, et al., one of ordinary skill in the art would be led away from combining the cyanobacteria of Caudales et al. with Müller et al.

Accordingly, at least for the aforementioned reasons, the combination of Müller et al. with the other cited documents is inappropriate and does not patentably distinguish over the claimed invention. Therefore, the claims of the

present invention are patentable over the cited art. Other distinguishing characteristics of the claimed invention will be discussed below.

Regarding claim 5, Viseras et al. fails to disclose any evidence that clay minerals would be well-dispersed in SLNs and one of ordinary skill in the art would have no reason disperse clay minerals in SLNs.

Additionally, Viseras et al. is directed to rheological testing of clays while Müller et al. is directed to SLNs. Accordingly, the subject matter of Viseras et al. is nonanalogous art to that of Müller et al. and therefore *prima facie* obviousness is absent.

Regarding claim 7, Walker et al. provides pages and pages of listings of the chemicals contained in New Zealand lichens and the presence of norlichexanthone chemicals, among many other chemicals, does not provide the motivation for one of ordinary skill in the art to integrate those particular chemicals into lipid nanoparticles. The disclosure in Walker et al. that lichen constituents have been used in folk medicine does not provide the required motivation since Walker et al. does not disclose that norlichexanthone chemicals have been specifically used for any treatments. Moreover, no evidence has been provided that the norlichexanthone chemicals disclosed in Walker et al. would provide adequate loading in lipid particles. Additionally, as stated above, there is no reason for one of ordinary skill in the art to modify Müller et al. to include marine biomasses instead of the synthetic lipids it is directed to.

Regarding claim 10, the Office Action has not identified any lipid microspheres or nanospheres made of material from microalgae, macroalgae, marine fungi, cyanobacteria, or marine bacteria cultivated in the presence of clay minerals.

Claim 12 recites heating microalgae, macroalgae, marine fungi, cyanobacteria, or marine bacteria. The Office Action has not identified where this is done in the cited art.

Regarding claim 13, Muller et al. discloses in the paragraph bridging pages 162-163 that for both hot homogenization and cold homogenization the lipid is melted. This shows that the processes of Muller et al. and claim 13 are different and that therefore claim 13 is patentable over the cited art.

Regarding claim 14, the cited art fails to disclose or suggest suspending the microalgae, macroalgae, marine fungi, cyanobacteria, or marine bacteria in an organic solvent with subsequent high pressure homogenization, spray drying or lyophilization, and subsequent redispersing and high pressure homogenization.

Regarding claim 15, the cited art fails to disclose or suggest forming the emulsion and then dissolving the emulsion in an organic solvent, adding a co-surfactant, and eventually doing high pressure homogenization.

Regarding claims 21-24, 26, 27, 32, 33, 34, 35, 36, and 37, the cited art does not disclose the respective recitations.

Regarding claim 25, no multiresistant strains are disclosed in the cited art.

Regarding claim 31, the cited art fails to disclose a method to obtain simultaneous immunostimulation.

New claims 38-50 have been added and are patentable at least for the reason that they depend from a patentable base claim.

Claims 1-19 and 31-38 have been amended and new claims 38-50 have been added. Support for the claim amendments and the new claims can be found, for example, in the claims as filed and in the specification as filed on the second paragraph.

Applicants respectfully request a three month extension of time for responding to the Office Action. **The fee of $525.00 for the extension is provided for in the charge authorization presented in the PTO Form 2038, Credit Card Payment form, provided herewith.**

If there is any discrepancy between the fee(s) due and the fee payment authorized in the Credit Card Payment Form PTO-2038 or the Form PTO-2038 is missing or fee payment via the Form PTO-2038 cannot be processed, the USPTO is hereby authorized to charge any fee(s) or fee(s) deficiency or credit any excess payment to Deposit Account No. 10-1250.

In light of the foregoing, the application is now believed to be in proper form for allowance of all claims and notice to that effect is earnestly solicited.

Respectfully submitted,
JORDAN AND HAMBURG LLP

By C. Bruce Hamburg
C. Bruce Hamburg
Reg. No. 22,389
Attorney for Applicants

and,

By Ricardo Unikel
Ricardo Unikel
Reg. No. 52,309
Attorney for Applicants

Jordan and Hamburg LLP
122 East 42nd Street
New York, New York 10168
(212) 986-2340

enc: Form PTO-2038